



WEEK ENDING DECEMBER 5, 2014

OPP Weekly Activity Report

Highlights Include:

Page

2	<i>Registration Division QA/QC and PPLS Upload of Electronic Labels</i>
2	<i>Meeting with Fumigant Task Forces</i>
2	<i>Insect Repellent Seminar at CDC Malaria Branch</i>
3	<i>Exclusive-Use Data Protection Extension Granted for Fenpyroximate Reg.</i>
3	<i>US Delegation to CCPR Sends Chemical Nominations to eWG on Priorities</i>
3	<i>Section 18 Quarantine Exemption Request Authorized for use of Potassium Chloride to Control Zebra/Quagga Mussels</i>
4, 10	<i>Meeting with China's Institute for Control of Agrochemicals, Ministry of Agriculture (ICAMA)</i>
4	<i>Regulators-In-Residency Visit: VA Dept of Ag and Consumer Services</i>
5	<i>PPDC Public Health Workgroup Conference Call</i>
5	<i>SmartLabel External Pilot Workshop</i>
5	<i>Experimental Use Permit (EUP) Extension for Acibenzolar</i>
7	<i>Final Work Plan Signed for Etridiazole</i>
8	<i>Suspensions Lifted for Two Pyrethrins Products in Product Reregistration</i>
8	<i>Propargite Final Work Plan (FWP) Signed!</i>
9	<i>Third EPA, FWS, NMFS, and USDA Workshop on Assessing Risks to Federally Listed Threatened and Endangered Species</i>
10	<i>SETAC North America Annual Meeting</i>
10	<i>GHS News</i>
11	<i>Collaborative for Testing Viruses Launched</i>
12	<i>Bed Bugs in Schools Webinar</i>
12	<i>Presentation on Biotechnology Regulation to Central American Regulators</i>
12	<i>BPPD Staff Speak to McKinley Tech HS Students about Biotechnology</i>
13	<i>Meeting held with the Council for the Advancement of Pyrethroid Human Risk Assessment on PBPK modeling</i>
14	<i>EPA & Health Canada Identify Enhancements to Joint Review Process for Antimicrobials</i>
15	<i>New Guidance for Companies on Emerging Pathogens</i>
15	<i>Pesticide Program Dialogue Committee Meeting Cancelled for December</i>

REGISTRATION DIVISION

Registration Division QA/QC and PPLS Upload of Electronic Labels RD has adopted a new e-label process in which electronic labels and letters are e-stamped and e-signed. QA/QC of the documents are performed within the division, and the letters and labels are automatically uploaded onto PPLS twice a day. For the two-week period of November 16-29, 2014, **97** product labels from RD were uploaded to PPLS. **Seventy-four** of the labels were automatically uploaded to PPLS via the new electronic process, while **23** labels were scanned then uploaded to PPLS by contractors. Over the course of the two weeks, RD's QA/QC Team reviewed **57** electronic decision letters/labels. The QA/QC team consists of members from each product branch: S. Adeeb/HB, A. Balan/FHB, M. Muhammad/FB, J. Gaines/IVB1, C. Petrella/IVB2, and J. Marchese/IVB3. (Jennifer Urbanski, 703/ 347-0156; Shaunta Hill, 347-8961)

OPP Meeting with Fumigant Task Forces On November 20, 2014, members of the Registration Division, Pesticide Re-evaluation Division, and Health Effects Division and including the Office of General Counsel met with representatives of the Methyl Bromide Industry Panel (MBIP), Chloropicrin Manufacturers' Task Force (CMTF), and Metam Task Force to discuss data matrix revisions requested under the reregistration of chloropicrin. The requested additional data citations include field volatility studies used by HED to determine the necessary buffer zones and special studies that were called in on the reregistration Data Call-In (DCI) to fulfill requirements on fumigant buffer zone posting signs, community outreach and education program special study, training for applicators supervising fumigations, and training materials for handlers. The Task Forces expressed their concerns with the addition of these citations onto the data matrices under reregistration. OGC and the Task Force representatives plan to have a conference call in the near future to continue the legal aspects of these data citations. (Erin Malone, 703/347-0253)

Insect Repellent Seminar at Centers for Disease Control and Prevention (CDC)

Malaria Branch On November 24, 2014, S.C. Johnson made a presentation to the CDC Malaria Branch that was broadcast through conference call and on-site. Thomas Putzer provided an overview of repellent work and the "Base of the Pyramid" program's philanthropic efforts around malaria elimination. This work is sponsored by Fisk Johnson of S.C. Johnson and Son, Inc. The base of the pyramid program and some repellent work is also performed in cooperation and in partnership (but without financial support) of the Bill and Melinda Gates Foundation. The company is currently developing a number of new consumer repellent products for use indoors and as personal protection measures in addition to their current line of repellents to decrease malaria and other mosquito-borne disease transmission. (Kevin Sweeney, 703/305-5063) [details at:

<http://www.scjohnson.com/en/press-room/fact-sheets/09-10-2009/Base-of-the-Pyramid.aspx>

Exclusive-Use Data Protection Extension Granted for Fenpyroximate Registration

On November 25, 2014, RD granted a request from Nichino America, Inc. for a three-year extension period of exclusive-use data protection period for selected data under the Fenpyroximate Technical (EPA Registration 71711-18) for hops, mint, okra, peppers, watermelons, eggplant, strawberries, mandarin orange, lemons, limes, and grapefruit. The supporting data submitted by the applicant and reviewed by EPA showed that fenpyroximate plays a significant role in an integrated pest management program (IPM), and in managing pest resistance. Exclusive-use protection for data, which complies with 40 CFR § 152.83(c), will expire on April 27, 2017. (Driss Benmhend, 703/308-9525)

U.S. Delegation to the CCPR Sends Chemical Nominations to the eWG on Priorities

On November 25, 2014, chemical nominations were submitted on behalf of the United States Delegation to the Codex Committee on Pesticide Residues (CCPR) to the Chair of the Electronic Working Group on Priorities (eWG). The nominations, which were due by November 30, 2014, requested scheduling for new compound evaluations and reevaluations for consideration by the CCPR and review by the Joint Meeting on Pesticide Residues (JMPR). The requisite nomination forms for each compound were submitted for **3** new compounds (including 1 biopesticide), **5** previously reviewed chemicals not currently scheduled for follow-up evaluation, and additional uses for **8** chemicals currently scheduled for review. Per an agreement with the FAO JMPR Secretariat, the US Delegation was also able to add additional commodities to the 2015 JMPR review schedule for difenoconazole (dry pea and dry bean) and flutiafol (broccoli, cabbage, celery, cotton, lettuce (head and leaf), maize, mustard greens, oilseed rape, sorghum and spinach) since these uses are expected to be registered in the United States before the September, 2015 JMPR meeting. (Barbara Madden, 703/305-6463)

Section 18 Quarantine Exemption Request Authorized for use of Potassium Chloride to Control Zebra/Quagga Mussels

On November 26, 2014, a Section 18 quarantine exemption was authorized to the Minnesota Department of Agriculture for use of the unregistered chemical, potassium chloride, formulated as muriate of potash for treatment of designated areas in **Christmas Lake** and **Lake Independence** in Hennepin County, Minnesota to control invasive zebra and quagga mussels. These invasive mussels have a variety of detrimental environmental and recreational impacts. This is the first request for this use in Minnesota. The quarantine exemption expires November 26, 2017. (Keri Grinstead, 703/308-8373)

Section 18 Specific Exemption Request Authorized for International Space Station

Use On November 26, 2014, a section 18 specific exemption was authorized to NASA (National Aeronautical Space Administration) for use of the unregistered chemical, ortho-phthalaldehyde, immobilized to a porous resin to treat the International Space Station internal active thermal control system coolant fluid for control of aerobic/microaerophilic water bacteria and unidentified gram negative rods. This is the fourth year an exemption has been authorized and NASA is working with EPA toward a registration for this use. (Andrea Conrath, 703/308-9356)

Registration Division Participates in Pesticide Management Meeting with China's Institute for Control of Agrochemicals, Ministry of Agriculture (ICAMA)

On December 1-2, 2014, members of the Registration Division (Jeff Herndon, Barbara Madden, and Jennifer Urbanski) participated in a two-day meeting with four representatives from China's Institute for Control of Agrochemicals, Ministry of Agriculture (ICAMA), including the Deputy Director, Liu Xue. FEAD coordinated the visit of the ICAMA officials and the main focus of the meeting was regarding the registration of minor uses and efficacy data review. Dr. Yuan (ICAMA) made a presentation on the Minor Use Program in China. Jerry Baron (IR-4) presented an overview of the Interregional Project No. 4 program. Barbara Madden (RD) and Dan Kunkel (IR-4) gave presentations on the regulation of minor crops in the United States, the ongoing crop group initiative and the IR-4/EPA minor use joint review program with Health Canada's Pest Management Centre and Pest Management Regulatory Agency. Dr. Jennifer Urbanski (RD) spoke regarding efficacy data requirements and efficacy data review for invertebrates in the Office of Pesticide Programs. This was a very productive meeting and there were some lively discussions. Special thanks to James Lin of EFED and Jenny Tao of AD who served as interpreters and did a great job helping us communicate. (Barbara Madden, 703/305-6463; Jennifer Urbanski, 347-0156)

Regulators-In-Residency Visit: Virginia Department of Agriculture and Consumer Services (VDACS)

As part of RD's Regulators in Residency (RIR) program, Liza Fleeson, Program Manager of the Office of Pesticide Services at VDACS, spent the first week, December 1-5, 2014, with OPP. The program, in its second year, seeks to foster communications and relationships with our state partners. Ms. Fleeson participated in meetings on various topics, including FEAD's first SmartLabel Pilot Program meeting, OECA updates, pollinator protection, misbranding and labeling consistency, spray drift issues, and bilingual pesticide labeling. Of particular note, Ms. Fleeson attended a meeting between OPP and officials from the People's Republic of China's Institute for Control of Agrochemicals, Ministry of Agriculture (ICAMA). She gave a presentation to this group on the role of state lead agencies in US pesticide regulatory activities. The responsibility for scheduling and administering the RIR program was recently transferred from RD's Immediate Office

to MUERB's Emergency Response Team. (Andrea Conrath, 703/308-9356; Tawanda Maignan, 308-8050)

Pesticide Program Dialogue Committee (PPDC) Public Health Workgroup

Conference Call On December 2, 2014, OPP hosted a conference call with the members of the PPDC Public Health Workgroup. The meeting was attended by representatives of RISE (Responsible Industry For A Sound Environment), CSPA (Consumer Specialty Products Association), AMCA (American Mosquito Control Association), state of Florida as well as federal partners and OPP colleagues. Topics covered at the meeting included the mosquito labeling initiative to change certain mosquito control product labeling to be more clear and useful to the user community. Also discussed was a new communications tool for professional applicators to hand to consumers when seeking to clarify the risk differences between a concentrated product and the diluted form. The workgroup concluded with a discussion of other topics to include in the next meeting. (Susan Jennings, 706-355-8574; Susan Lewis, 703/308-8009)

Child-Resistant Packaging (CRP) Overview Presentation On December 3, 2014, Rosalind Gross gave an overview of Child-Resistant Packaging (CRP) for the Registration Division. The presentation explained the CRP regulations, what is required to register products needing CRP, and how to determine a toxic amount for products in unit dose packaging. There were numerous questions such as how to test if a package meets CRP requirements. (Rosalind Gross, 703/308-7368)

SmartLabel External Pilot Workshop On December 4, 2014, members of the SmartLabel Team kicked off the external pilot with a workshop for participants going through the structured data model in order to gain necessary feedback to move forward with the initiative. EPA presenters walked through the draft model, user guide, style sheet, and style sheet instructions. The SmartLabel group will meet again with pilot participants to gather feedback in late January. Registrants participating in the voluntary SmartLabel Pilot are: Bayer CropScience, Clorox, Dow AgroSciences, EcoLab, Marrone Bio, Reckitt Benckiser, SePRO, Syngenta, and United Industries Corporation. The pilot is expected to last about 6 months. These companies will develop and submit for testing a number of pesticide product labels that conform to the SmartLabel specifications. EPA is also making the documents used in the pilot, such as the data model and draft xml specifications, available on our website. Interested stakeholders are encouraged to comment on these documents. At the end of the pilot program, EPA hopes to implement a voluntary SmartLabel system for all registrants. (Maggie Rudick, 703/347-0257; Dominic Schuler, 347-0260; Erin Malone, 347-0253; Autumn Metzger, 305-5314)

Experimental Use Permit (EUP) Extension for Acibenzolar OPP generally does not receive many EUPs but the Fungicide Branch approved recently the extension of

an existing EUP for Acibenzolar to [December 31, 2015](#) for grapefruit, pears and apples. It was scheduled to expire December 31, 2014. Acibenzolar is a plant growth regulator that does not kill plant fungi and bacterial pests, but rather induces SAR (systemic acquired resistance) in the plant against pests. One of the target pests is citrus canker in Florida which is a serious problem. Acibenzolar it will be used for 2015 in 11 States on a maximum of 1000 acres, and up to 800 pounds of product. (Tony Kish, 703/308-9443)

Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions					
State/Federal Agency	Chemical Emergency Exemption Number	Product Name EPA Reg/ File Symbol	Crop/Site	Pest	Authorization Date
Quarantine Exemption(s)					
Minnesota Department of Agriculture	Potassium Chloride (15-MN-01)	Muriate of Potash (Unregistered)	Christmas and Independence Lakes	Zebra & Quagga Mussels	11/26/2014
Keri Grinstead, 703/308-8373					
Specific Exemption(s)					
National Aeronautical Space Administration (NASA)	Ortho-phthalaldehyde (14-DO-02)	Unregistered Product	International Space Station	Aerobic/ Microaerophilic water bacteria and Unidentified gram negative rods	11/26/2014
Andrea Conrath, 703/308-9356					

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch granted:					
Fludioxonil	Syngenta Crop Protection	100-1530	R320	12/3/2014	12/2/2014
Erin Malone, 703/347-0253					
Octanoic acid, copper salt	W. Neudorff GMBH KG	67702-2	R340	2/2/2015	11/13/2014
Lindsay Roe, 703/347-0506					
Ethephon	NuFarm Limited	35935-81	R351	1/15/2015	11/26/2014
Craig Reeves, 703/347-0486					
Tebuconazole	Luxembourge-Pamol, Inc.	42519-27	R351	12/1/14	11/21/2014
Marcel Howard, 703/305-6784					
The Fungicide Herbicide Branch granted:					
Isoxaflutole	Bayer CropScience	264-1067	R340	1/8/2015	12/2/2014
Rowland Grant, 703/347/0254					
Glufosinate	Ammonium, LLC	89707-1	R351	11/28/2014	11/25/2014
Dianne Morgan, 703/305-6217					
Pyroxasulfone	K-I Chemical U.S.A. Inc.	63588-91	R351	1/29/2015	12/3/2014
Erick Kraft, 703/308-9358					

The Herbicide Branch granted:					
Pendimethalin	United Suppliers, Inc.	33270-28	R300	1/5/2015	12/3/2014
Sarah Meadows, 703/347-0505					
Atrazine	United Suppliers	33270-9	R340	12/15/2014	12/4/2014
Shanta Adeeb, 703/347-0502					
The Invertebrate-Vertebrate Branch 1 granted:					
Tetramethrin	Chemsico	9688-326	R310	12/1/2015	11/24/2014
Maggie Rudick, 703/347-0257					
Prallethrin	Rainbow Technology Corporation	13283-31	R340	1/2/2015	11/21/2014
Jennifer Gaines, 703/305-5967					
The Invertebrate & Vertebrate Branch 2 granted:					
Canola Oil	W. Neudorff GMBH KG	67702-6	R340	1/8/2015	11/25/2014
Carlyn Petrella, 703/347-0439					
Metaflumizone	BASF Corporation	7969-226	R351	1/13/2015	11/25/2014
Michael Walsh, 703/308-2972					
The Invertebrate & Vertebrate Branch 3 granted:					
Abamectin	Axion AG Products, LLC	89167-11	R340	12/14/2014	11/26/2014
Jacquelyn Marchese, 703/347-0559					
PRIA Categories					
R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix (3) (4) ; R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging (2) (3) ; R320 – New product; new physical form; requires data review in science divisions (2) (3) ; R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements) (2) (3) ; and R351 – Amendment adding a new unregistered source of active ingredient (2) (3) .					

PESTICIDE RE-EVALUATION DIVISION

Final Work Plan Signed for Etridiazole. A Final Work Plan was signed for etridiazole (PC Code 084701) on November 28, 2014. This work plan addresses public comments received concerning the Preliminary Work Plan (PWP), which was posted in the etridiazole registration review docket (EPA-HQ- OPP-2014-0414). Etridiazole is a soil fungicide in the thiazole family registered for use to control primarily *Pythium* and *Phytophthora* soil water mold species. Etridiazole is also used to control bacteria in genus *Nitrosomonas*. Etridiazole is registered for use on field cotton, turf (golf courses), nursery stock, tobacco float bed seedling treatments, and greenhouse ornamentals as well as for mixing in potting soil for commercial greenhouse use. In addition, etridiazole has been approved for certain Special Local Need (SLN) greenhouse uses on tomatoes. There are currently no registered residential uses for etridiazole. Etridiazole is known by a variety of trade names, of which the most common is Terrazole. There are no updates in the etridiazole FWP since the PWP. (Margaret Hathaway, 305-5076)

Bispyribac-Sodium Final Work Plan Signed November 28. Bispyribac-sodium is a selective, post-emergent herbicide used to control grasses and weeds in both agricultural and non-agricultural settings. It is registered for use on rice, ornamental lawns, other turf (including golf courses and sod farms), canals, drainage ditches, marshes, lakes, ponds, and reservoirs. The FWP will be posted in docket number EPA-HQ-OPP-2014-0074. The Agency anticipates issuing a DCI for several environmental fate and ecological effects data requirements. (Moana Appleyard, 703-308-8175)

Suspensions Lifted for Two Pyrethrins Products in Product Reregistration. EPA Reg. #s 15297-14 (Bio-Groom Flea & Tick-14 Pyrethrin Dip Conc. For Dogs and Cats) and 15297-19 (Bio-Groom Ear Mite Treatment) were suspended on February 22, 2012 under FIFRA Section 3(c)(2)(B). The registrant subsequently submitted required data, which the Agency found to be acceptable. The Suspension Order for these products has now been lifted. (Moana Appleyard, 703-308-8175)

Zoxamide Final Work Plan Signed. A Final Work Plan for Zoxamide was signed on December 1, 2014. Zoxamide (PC Code 101702) is a non-systemic broad-spectrum benzamide fungicide registered for use to control fungicidal diseases (e.g., spot, downy mildew, rot, blight, mold, blotch) on select fruit and vegetable crops. Zoxamide is registered for use on cucurbit vegetables (melons, pumpkin, squash, and watermelon), grapes, potatoes (white/Irish), and tomatoes. The proposed new use of zoxamide on the crop group onion, bulb, and subgroup 3-07A was approved by the Agency in August 2014. The final work plan addresses public comments received concerning the Preliminary Work Plan (PWP), which was posted in the zoxamide registration review docket (EPA-HQ-OPP-2014-0391) in June 2014. The Agency plans to require several environmental fate, ecological effects, and human health studies for zoxamide through a Data Call-In Notice, expected to be issued in Jan-March 2015. (Tanja Crk, 703-308-8202)

Completion of Bioban P-1487 Product Reregistration Case. On December 2, 2014, all products containing the active ingredient 4-(2-Nitrobutyl) morpholine and Morpholine, 4,4'-(2-ethyl-2-nitro-1,3-propanediyl)bis- were sent to the Antimicrobial Division to complete the final phase of product reregistration. The completion of a product reregistration case is a milestone that signals the complete implementation of RED risk mitigation for the case. (Julia Stokes, (703) 347-8966)

Propargite Final Work Plan (FWP) Signed! The Propargite FWP was signed on December 3, 2014. Propargite is an organosulfite insecticide (acaricide/miticide) registered for use to control mites on a variety of field, fruit, and vegetable crops, as well as ornamentals. There are no registered residential uses of propargite. The propargite registration review docket opened in June 2014. The FWP provides a summary of substantive comments received during the public comment period

for the preliminary work plan (PWP) concerning anticipated data needs, expected risk assessments, or the estimated timeline identified in the PWP, and a summary of the Agency's responses to those comments. The comments did not result in changes to the anticipated risk assessments or timeline; however, a comment from the registrant resulted in a change to the anticipated data needs. The data call-in is expected to be issued in early 2015. The FWP will be posted to the registration review docket soon. See docket EPA-HQ-OPP-2014-0131 at www.regulations.gov. (Wilhelmena Livingston, 703-308-8025)

Mesotrione Final Work Plan Signed December 3. The FWP and supporting documents will be posted to the docket at EPA-HQ-OPP-2013-0779. The Agency plans to require environmental fate and ecological effects data for mesotrione through a Data Call-In Notice, which is expected to be issued in January- March of 2015. Mesotrione is a pre- and post-emergence selective herbicide registered for the control of broadleaf weeds on many agricultural and non-agricultural use sites. (Jolene Trujillo, 703-347-0103)

ENVIRONMENTAL FATE & EFFECTS DIVISION

Third EPA, FWS, NMFS, and USDA Workshop on Assessing Risks to Federally Listed Threatened and Endangered Species. Staff and management from EPA (OPP and OW), the U.S. Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the U.S. Department of Agriculture (USDA) participated in the third week-long interagency ESA workshop in Falls Church, VA from November 17 – 21, 2014. The purpose of the workshop was to further develop the interim scientific approaches for assessing pesticide risks to federally listed threatened and endangered species (and their designated critical habitats) in the context of the three pilot chemicals (chlorpyrifos, diazinon, and malathion) for which BEs are scheduled to be completed by late summer of 2014. Specifically, the goals of the workshop were to further discuss and come to agreement on the process for exposure modeling in terrestrial and aquatic environments; development of a weight-of-evidence approach that connects exposure to effects, including data and study validity criteria, lines of evidence for species' groupings, and methods for weighing and aggregating lines of evidence; and an understanding of the information needed in the BE to inform Step 3 (the BiOps). Agreements were reached on a variety of issues related to geospatial pesticide use site mapping, effects thresholds for Steps 1 and 2, a process for reviewing and ensuring data quality and relevancy, methods for deriving terrestrial and aquatic exposure in Step 2, including a discussion of data output for use in Step 3, use of monitoring data, lines of evidence that can be applied across species' groupings, weight-of-evidence criteria and use of three categories (high, medium, low) to rank various lines of evidence. Topics requiring further discussion include the level of quantitative/qualitative mixture analysis in the BE and the methods by which

information from Steps 1 and 2 of the BE is integrated and synthesized into the Step 3 jeopardy/no jeopardy decision. (Anita Pease, 703-305-0392).

EFED Presents at SETAC North America Annual Meeting. During the 35th Annual Society of Environmental Toxicology and Chemistry (SETAC) meeting, Meghan Radtke (EFED) presented a poster on EPA's pollinator risk assessment framework, highlighting a case study with cyantraniliprole. Meghan also gave a talk on OPP's current challenges in determining testing requirements for non-target plants. During the same meeting, Catherine Aubee presented posters and platforms on the sensitivity of amphibians compared to their surrogates and a risk assessor's perspective on ecological model development and implementation. She also co-hosted an affiliated workshop that outlined current challenges and paths forward for reptiles and amphibians in ecotoxicology and risk assessment. In a session on ecological risk assessment of pyrethroid insecticides, Keith Sappington discussed the current status and issues associated with EPA's assessment of ecological risks of pyrethroid insecticides. Melissa Panger and Kris Garber presented on various topics related to revising the methodology associated with assessing risks of pesticides to listed species. Kris Garber also presented a poster focused on the TIM and MCnest models. Justin Housenger also presented posters on an analysis of the WebICE model and an overview of the Audrey III model. (Meghan Radtke, 703-347-0229; Catherine Aubee, 703-347-8029; Keith Sappington, 703-605-0581; Kris Garber, 703-347-8940; Melissa Panger, 703-305-6136; Justin Housenger, 703-305-6060).

FIELD & EXTERNAL AFFAIRS DIVISION

Chinese Delegation Visits OPP. On December 1-2, FEAD coordinated the visit of four officials from China's Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA), including the organization's Deputy Director. Topics of discussion included joint reviews of pesticides, efficacy and safety evaluations, and minor use/specialty crops. The Director and Deputy Director of the IR-4 program joined the 2-day meetings, as did a state representative who shared about efficacy and state roles. RD delivered excellent presentations throughout, and the Chinese delegation also gave presentations on efficacy and crop groupings. As we change our relationship with ICAMA going forward, the joint presentations and shared experiences from both sides may help set the stage for a new way of interacting. (Barbara Madden, RD, 305-6463; Martha Shimkin, FEAD, 305-5160)



GHS News. The United Nation's subcommittee of experts on the Globally Harmonized System of Chemical Classification and Labelling (GHS) will meet in Geneva on December 10-12. The Policy & Regulatory Services Branch

represented EPA in the U.S. delegation's preparations for the meeting and in developing the U.S. position. PRSB coordinated EPA's review of working papers on hazard classification criteria and test methods, and paneled stakeholder outreach meetings alongside OSHA, DOT, CPSC, and the Coast Guard. The U.S. delegation, led by OSHA, will be heading to Geneva in the next few days to wrap up the program of work for the 2013-2014 biennium and to discuss adoption of the program of work proposed for the 2015-2016 biennium. EPA will continue to stay involved in the discussions electronically during this meeting by providing technical support to the U.S. delegation. (Lily Negash, 347-8515)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Collaborative for Testing Viruses Launched. The EPA is interested in adopting the new OECD Quantitative Method for substantiating bacterial, virucidal, and fungicidal claims for antimicrobial products. Collaborative studies designed to assess the method's performance (i.e., assessment of variability) across labs have previously been conducted by MLB and its stakeholders on several bacteria. A collaborative for testing viruses was launched by MLB this week. MLB and three stakeholder labs will participate in the study. In this study, analysts proficient at conducting the OECD method and virus recovery assays will be asked to evaluate a set of treatments (EPA-registered disinfectant products) against feline calicivirus (a non-enveloped surrogate of norovirus) using a blinded, randomized and replicated study design. The treatments represent important classes of active ingredients; quaternary ammonium compounds, alcohol, sodium hypochlorite (reference standard), citric acid, and hydrogen peroxide. The Standard Operating Procedure and the Collaborative Study Protocol were submitted to the labs for review. The goal is to have the data generation completed by the end of March 2015. In addition, Michelle Cottrill of MLB is being trained on the virology procedures to support the collaborative effort. (Jason Duncan, 410-305-2619 and Michelle Cottrill, 410-305-2955)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

 OPP FOIA Request Status Report for Nov. 17- 28, 2014 							
Requests Received		Requests Closed			Requests Open		
FY15	This Week	FY15	FYTD	This Week	FY15	Prior Years	Total
97	15	31	69	12	66	304	370

(Ana Espinoza, 703-347-0102)

Archival & Removal of Pesticide Web Content. The ITRMD Web Team has been working with FEAD to identify and process Pesticide web content to be archived or removed from the old Pesticides website. Recent activities have resulted in the removal of web content to include the Pesticide Registration Manual (Blue Book), Pesticide Label Review Manual, Pollinator Protection, Soil Fumigants, and PPDC web pages and documents that have been transformed and published in the Drupal WebCMS environment. Other web activities include ongoing efforts with OEI for the archival of old Pesticides web content that will not be published in the Drupal WebCMS, but continues to have value and historical significance which includes Pesticide Residue Analytical Methods, CARAT and TRAC web content, and older PPDC web content not published in Drupal. (Les Hoot, 703-305-0876)

Bed Bugs in Schools Webinar. The ITRMD Web Team posted details of the December 16, 2014, Bed Bugs webinar on the Website. This webinar, hosted by EPA, will present the challenges schools face concerning bed bugs and an IPM strategy that engages the entire school community to successfully manage bed bugs. Additional information is available at <http://www2.epa.gov/bedbugs/december-16-2014-epa-host-webinar-bed-bugs-schools> . (Christine Tran 305-1577)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

BPPD Staff Presents on Biotechnology Regulation to Central American Regulators

From November 17-21, a group of 45 regulators from Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, and Panama attended a biotechnology course in San Jose, Costa Rica, sponsored by USDA's Food and Agriculture Service (FAS). This regulatory workshop was developed by the University of Missouri's Economics and Management of Agro-biotechnology Center. BPPD staff presented overviews of EPA's regulatory process for plant-incorporated protectants, including food and feed safety assessment, history of our regulatory development, a Bt-maize case study, and risk communication considerations. Professors from the U.S. and Brazil also made presentations on the economics of biotechnology and genetics and plant breeding. Central American countries are signatories to the Cartagena Protocol and are developing prescribed legislation and regulatory systems to handle biotechnology-derived crops and pest control agents. IICA, the Inter-American Institute for Cooperation on Agriculture, the U.S. State Department, and USDA-FAS staff at the U.S. embassy in San Jose provided a well-organized workshop with excellent learning opportunities for the regulators in attendance. (Chris Wozniak, 308-4043).

BPPD Staff Speak to McKinley Technical High School Students about

Biotechnology On December 2, representatives from OPP-BPPD, FDA-CFSAN, APHIS-BRS, Monsanto, and a professor from Catholic University spoke to a group of

high school students, many of whom are enrolled in a biotechnology education program at McKinley HS in Washington DC. The three year biotechnology program trains students in both theoretical and applied (laboratory) aspects of biotechnology as it relates to pharmaceutical and agricultural applications. The principle force behind this program, Dr. Ericka Senegar-Mitchell, has significant experience in industrial pharmaceutical laboratories as well as in many aspects of education she shares with her students. The presentations were followed by a question and answer period, which allowed the students to interact directly with speakers, follow-up on areas of interest, and consider recent developments that could provide novel foods derived from biotechnology. (Chris Wozniak, 308-4043; Mike Mendelsohn, 308-8715).

HEALTH EFFECTS DIVISION

Meeting held with the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) on PBPK modeling:

On November 6, industry representatives presented the status of the physiologically-based pharmacokinetic (PBPK) models under development for deltamethrin and permethrin. Several HED staff attended. CAPHRA representatives also discussed proposals for extending these PBPK models to other pyrethroids using 'read across' approaches. The upcoming May SAP was also discussed. (Anna Lowit, 308-4135)

HED Staff Attend Demonstration on The International Uniform Chemical Information Database (IUCLID):

Christine Olinger and Rick Whiting, HED, attended a Webinar by Tina Wadhera of SC Johnson UK demonstrating the use of IUCLID for the pesticide submission process in Europe. An OPP workgroup on DER composers has been looking at methods for submission of structured data for ease of review and insertion into databases. (Chris Olinger 305-5406)

Section 18 Assessment for Control of Zebra Mussels in 2 MN Lakes: HED assessed the potential for exposure associated with a Section 18 request for the use of muriate of potash (potassium chloride) to control invasive zebra mussels in 2 MN lakes. A similar use pattern had been assessed previously for control of the mussels in TX and VA. HED concluded that there was no concern for occupational exposure since applications will be made only by certified applicators, due to the method of application, and the use of personal protective equipment in accordance with the Section 18 label. No recreational exposure is expected since the treatment areas are not open to the public; finally, due to the relatively small treatment area compared with the entire volume of the 2 lakes, there is no concern for exposure to fish. (Christina Swartz, 305-5877)

HED Scientist Participates in OECD Conference Call: On December 1st, Liz Méndez (HED) participated on a conference call to discuss revisions to OECD

guidelines 421 and 422. Used primarily as screening level assessments, these guidelines (Reproduction/Developmental Toxicity Screening Tests) evaluate a number of parameters to determine the potential of a chemical to cause developmental or reproductive perturbations. The revisions to the guideline would add measurements of thyroid hormones (T4), and histopathology, as well as, assessment of estrous cyclicity. Although there was a proposal to add enumeration of corpora lutea and fixation/histopathological evaluation of the pituitary, the group concluded that for a screening level study these endpoints would result in a significant increase in the level of effort and would – at this stage of the chemical’s testing – contribute very little valuable information. (Liz Méndez, 305-5453)

ANTIMICROBIALS DIVISION

EPA and Health Canada Identify Enhancements to Joint Review Process for Antimicrobials. On Monday November 24, 2014, regulators from the Antimicrobials Division hosted a conference call with Health Canada to review and identify potential enhancements to the process for handling reviews of applications for antimicrobial pesticide products for sale/distribution in both Canada and the US. The brief call focused on reestablishing primary points of contacts, target review times, and guidance to provide to companies (e.g., indicating in the cover letter that the application is for a product intended to be marketed in both Canada and the US with a common label). EPA and Health Canada will continue to collaborate on the joint reviews of Canadian/US antimicrobial products. (Lance Wormell, 603-0523)

AD E-Label Process Implementation. AD has been piloting a new E-Label Process, based on recommendations from the Lean Label Review, Approval and Posting Team. In the new process, electronic labels and letters are e-stamped and e-signed, QA/QC of the documents is performed within the division, and the letters and labels are automatically uploaded onto PPLS twice a day. Benefits of the new process have included higher quality documents, faster posting to PPLS (average of 2-3 days compared to 12-18 days), and reductions in use of paper and scanners.

Week	# of Labels Processed Electronically with the New E-Label Procedures	# of Labels Manually Scanned and Uploaded with the Old Procedures
11/9/14 - 11/15/14	6 (24%)	19 (76%)
11/16/14 - 11/22/14	6 (35%)	11 (65%)
11/23/14 -11/29/14	12 (41%)	17 (59%)

(Elizabeth Watkins, 347-0241; Stacey Grigsby, 305-6440; Julie Chao 308-8735)

EPA and FDA Meeting on Regulatory Processes and Science Assessments On Tuesday, December 2 AD, HED and RD met with FDA’s Center for Food Safety and

Applied Nutrition to discuss the regulatory and risk assessment process for Food Contact Notifications and Food Additive Petitions. We also discussed a pending Memorandum of Understanding between EPA and FDA on information sharing for substances that may be dually regulated. (Elizabeth Watkins, 347-0241).

New Guidance for Companies on Emerging Pathogens AD developed a new webpage to provide companies with guidance on how to refer to CDC guidance on products to use against the emerging pathogen Enterovirus D68 in non-label communications with their customers and the user community. In addition, the Enterovirus guidance includes and the Ebola guidance to companies was expanded to include products with hospital equivalent claims for non-health care use sites (such as schools or residences). EPA and CDC discussed this change and CDC revised their non-health care recommendations accordingly. Both guidances instruct companies that they should only refer to products that are recently registered (since 2010) or have been confirmed as efficacious under the ATP, or have been confirmed as efficacious through submission of new data developed under a new more rigorous method.

IMMEDIATE OFFICE OF THE DIRECTOR

Pesticide Program Dialogue Committee Cancelled for December 11-12, 2014 The PPDC and Work Groups have **cancelled** the December meetings. Dates set for 2015 for PPDC are as follows: May 14-15, 2015, and October 22-23, 2015. Closer to these dates and times, agendas will be posted on the PPDC website at: <http://www.epa.gov/pesticides/ppdc/>.